MEMORANDUM

June 16, 1999

SUBJECT: Response to Public Comments on the Preliminary Risk Assessment[s] for the Organophosphate Bensulide

FROM: Loan Phan, Chemical Review Manager
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Office of Pesticide Programs

TO: OPP Public Docket for Bensulide
Docket # 34132

Introduction

This document addresses public comments that were received in response to EPA's Notice of Availability (63 FR 43175, August 12, 1998) of preliminary risk assessment[s] for the first nine organophosphate chemicals: azinphos-methyl; bensulide; ethion; fenamiphos; isofenphos; naled; phorate; profenophos; and terbufos. Part I of this document addresses comments specific to bensulide. All of the comments specific to the bensulide human health assessment were made by Gowan Company, the registrant. Comments relating to the environmental and ecological assessments were made by Gowan Company and Mr. Carl Bell, a weed science specialist.

Part II focuses on non-chemical-specific comments. "Non-chemical-specific" means that the comment was submitted to the OPP Public Dockets for each of the nine chemicals or for a significant sub-set of the nine. Also, these non-chemical-specific comments generally apply to regulatory or science policy issues that are not unique to any one of the risk assessments.

Note: Since the close of the public docket in October, 1998, refinements have been made to both the Human Health and Ecological risk assessments for bensulide – endpoints have been revised based on new studies submitted by the registrant in May, 1999, and the risk assessments have been refined significantly. Where appropriate, these studies and refinements are noted to provide an update on the status of comments made in reference to the preliminary risk assessments. These updates are noted in *italics*. For further details on how these studies and refinements impacted the risk assessments, refer to the revised human health and ecological risk

assessments that are now available in the Public Docket and on the Agency's website: **www.epa.gov/pesticides.**

Part I: Bensulide-Specific Comments and Responses

A. Response to Comments on the Preliminary Human Health Risk Assessment (HED chapter)

1. Dietary Risk Assessment

Gowan Company ("Gowan"): A metabolism study in rats had been classified unacceptable until data were submitted showing that reasonable efforts had been made to identify metabolite "H." Gowan Company submitted a report identifying efforts made to characterize the metabolite.

EPA Response: The submitted data resulted in upgrading the study classification status to acceptable. This study, along with 4 previously submitted metabolism studies, satisfies requirements for a metabolism study in rats.

Gowan: A subchronic neurotoxicity study was requested by the Agency in 1991. Gowan requested a waiver for this study because they said that the study would provide no significant new information and was not needed to evaluate bensulide.

EPA Response: The requirement for a subchronic neurotoxicity study was waived by the Hazard Identification Assessment Review Committee and this study is **not** required at the present time. The HIARC made this decision because neuropathology was not observed in the acute hen or rat neurotoxicity studies or in any other toxicity studies.

Gowan: The chapter said that a tomato processing study must be submitted. Gowan commented that a tomato processing study has been submitted.

EPA Response: The tomato processing study has been reviewed.

Gowan : The HED chapter used a calculated dermal absorption value of 20%. This value was calculated by comparing oral and dermal LD50 values in rats. The HIARC later changed the dermal absorption value to a default value of 100%. Gowan objected to use of a 100% dermal absorption value and has submitted protocols for a 21-day dermal toxicity study and an acute dermal toxicity study.

EPA Response: The HIARC evaluated the dermal absorption of bensulide and other organophosphates in a meeting in December, 1998, and reduced the dermal absorption value to 10%. Since then, the registrant has completed the 21-day dermal toxicity study, and the Agency has incorporated the study into the revised risk assessment.

Gowan: An acute dietary analysis by the Agency using DRES found that margins-of-exposure (MOEs) for the most sensitive populations (infants and children) were 1500. An MOE of greater than 100 is considered protective for bensulide, and these MOEs did not exceed the Agency's level of concern. Gowan submitted an acute dietary analysis using DEEM which used per cent crop treated and found MOEs above 100,000. This dietary analysis was submitted for use in a cumulative risk assessment with other organophosphate pesticides.

EPA Response: The Agency has also refined its acute dietary analysis using DEEM, and has found risks to be below 1%. A cumulative risk assessment for organophosphate pesticides is not being conducted at this time.

Gowan: The endpoint selected by the Agency for short term dermal occupational/residential exposure of 1-7 days duration was based on plasma cholinesterase inhibition occurring after 14 days of treatment (the earliest measurement period) in a rat developmental study. Gowan objected to use of an endpoint determined after 14 days of treatment for use in risk assessments involving exposure of only 1-7 days duration.

EPA Response: Plasma cholinesterase inhibition occurring after 14 days of treatment with bensulide is believed to be similar to that occurring after 7 days of treatment. Although a 21-day dermal toxicity study was available, cholinesterase activity was not measured in this study and it was not suitable for use in risk assessments. Gowan has since conducted a 21-day dermal toxicity study that includes cholinesterase determinations -- that study has been completed, the Agency used that study to select a dermal exposure endpoint, and has incorporated these changes into the revised risk assessment.

2. Occupational & Residential Exposure (ORE) Assessment

(a) Gowan's comments from letter dated May 1, 1998. The format of the letter references specific aspects of the preliminary risk assessment (HED chapter) by page number and paragraph number, then provides excerpts of the HED chapter followed by the Gowan response. In order to facilitate review of this document, each specific Gowan comment in its entirety is reproduced below, followed by the Agency's response to the comment.

Comment 1

(assumptions used in the occupational exposure assessment): "Average workday interval represents an 8 hour workday..." (p. 41/par. 3)

We (Gowan) believe that agricultural workers or turf applicators will almost never apply bensulide as much as 8 hours per day....

EPA Response to Comment 1

The Agency does not concur with this comment and will address the specifics of this comment in the response to the more detailed Gowan ORE Comment 2 on this issue (see EPA Response to Comment 2 below). Additionally, it should be noted that this comment is not reflective of the standard Agency approach for addressing exposures. EPA uses a task-based exposure assessment approach. This approach accounts for the anticipated daily routines of the exposed population. For example, if agricultural applications by groundboom equipment are considered, it is likely that an applicator could work 8 hours or more doing nothing but spraying pesticides. In most other kinds of scenarios, however, this is not the case because the application method is efficient enough to treat a designated area in less than a typical 8 hour workday. For this reason, the Agency has developed standard estimates of acreage that are used for risk assessment purposes that eliminate the time factor and consider the application method and the characteristics of the application target. The use of bensulide on golf courses is a perfect example in that it is likely that an entire course could be treated in less than 8 hours, but on an application day the entire course would be expected to be treated. The Agency completed an assessment based on the assumption that bensulide could be used to treat a 36 hole golf course in one day (i.e., approximately 40 acres) using groundboom equipment. This is easily attainable given the efficiency of common groundboom equipment. The bensulide risk assessment also considered homeowner applicator scenarios in which the duration of the application event would be much less than 8 hours but it is anticipated that a homeowner would treat their entire lawn which, in this case, is considered to be 0.5 acres.

When post application exposure scenarios were considered for bensulide, it should be noted that the duration value used for adults was 4 hours per day and not 8 hours per day because the Agency recognized that typical turf management employees would not likely be engaged in activities contributing to exposure for entire workdays as these kinds of occupations typically require a diverse set of activities on each day. Additionally, the 4 hour value was used to account for homeowner turf and for recreational turf exposures. Toddler exposures were also assessed using a duration of 2 hours, the 95th percentile value for time spent outdoors derived from the 1997 U.S. EPA Exposure Factors Handbook.

Gowan is a member of the Outdoor Residential Exposure Taskforce (ORETF) and the Agricultural Reentry Taskforce (ARTF). *A turf transferable residue (TTR) study has been completed as part of these efforts, and was used by the Agency to refine exposure duration and chemical/application - based exposure factors in the revised risk assessment.*

Comment 2

(assumptions used in the occupational exposure assessment): "Daily areas and volumes.....to be treated in each scenario include [several assumptions follow]." (p. 41/par. 4)

We believe that the Agency's standard assumptions regarding the area treated are in some cases not applicable to bensulide.

Golf Courses: the Agency's estimates are at least an order of magnitude too high. To our knowledge, bensulide is used virtually entirely on golf greens, and a small amount may be used on tees. It is not used on fairways because the product is too expensive. This observation was noted elsewhere in the HED chapter [p. 39, par.1]. Most greens have a radius of 30 feet or less, but we will assume an upper limit of 50 feet. In this case, all of the greens on an 18-hole course would have a total area of 3.2 acres. If tees were treated, which is extremely unlikely, the total treated area would approximately double, to 6-7 acres. This is far less than the Agency's assumptions of 50 acres treated by professional turf applicators and 40 acres for granular tractor-drawn spreaders. The risk to such applicators is correspondingly an order of magnitude lower than the Agency has calculated.

It may be noted that golf course superintendents are highly-paid employees of the golf course in question. These people rarely if ever treat more than one golf course, and their occupational exposure to bensulide is correspondingly limited.

There are approximately 14,000 golf courses in the United States. Approximately 40% of these have 9 holes and approximately 50% have 18 holes. Only about 10% have 36 or more holes. It is our understanding that no single individual treats more than 36 holes. In few resort complexes which have more than 36 holes, responsibility for turf management is handled by more than one individual.

It is our understanding that a label statement restricting the use of bensulide on golf courses to the greens and tees only would have little or no impact upon the current use of such products. Such a restriction would enable the Agency to reduce its estimates of occupational and nonoccupational exposures from golf courses. Gowan cannot directly propose such an amendment to the Agency because all products which are actively sold for use on golf courses are registered by other companies (PBI/Gordon Corporation, The Scotts Company and United Horticultural Supply and/or its affiliated company Platte Chemical Company).

Other professional applications: A small portion of all bensulide use (less than 2 percent and, to our knowledge, possibly none at all) involves application by professional applicators who treat home lawns and public areas. The Agency has assumed that up to 5 acres per day may be treated with granular products using push-type spreaders or "bellygrinder" applicators, and 5 acres may be treated with EC products using backpack applicators.

Bensulide is no longer a product of choice by professional lawn care companies because of the development of new and less expensive products during the last decade. Assuming that a professional applicator does use bensulide, however, such an applicator would treat areas this large with mechanized equipment. Granular products are normally applied using a spreader pulled by a small garden tractor, and EC products are normally applied using a groundboom for larger areas or a low pressure handwand connected to a truck-mounted tank for smaller areas. Treatment of large areas by hand equipment would be an inefficient and unprofitable use of manpower because these application techniques are slower than applications using mechanized

equipment. We are told that one acre is a reasonable upper limit to assume for push-type spreaders and backpack sprayers, and "bellygrinders" are almost never used by professional applicators.

Chemigation (agricultural) applications: To our knowledge, the largest area which has been treated with bensulide at one time is 80 acres, not 350 acres, and this occurred only in the desert Southwest. Elsewhere, the maximum area treated is thought to be 40 acres.

Furthermore, for large treatment areas, Prefar 4-E Herbicide is transported and distributed in bulk containers, not in standard 2.5 gallon jugs. This reduces the exposures of pesticide handlers. Bulk containers constitute a closed system and the applicator makes only one connection from the bulk tank to the irrigation system. There is no "mixer/loader" in a chemigation system using a bulk container.

The Agency noted elsewhere in the HED chapter [p. 38, last line] that PHED exposure estimates for bulk handling are unfortunately not available. We agree, but we do not believe that this warrants using default assumptions (e.g., handling 210 - 2.5 gallon jugs of Prefar 4-E to treat 350 acres) which are known to be incorrect.

EPA Response to Comment 2

The Agency does not concur with the Gowan comments presented above. Comments are addressed individually below along with EPA's rationale for not accepting the comments.

Golf Course Use: Addressing the comments on the golf course use handler risk assessment hinges upon restricting bensulide to tees and greens. If the uses are restricted to tees and greens, the comments supplied by Gowan would be appropriate with the stipulation that a 36 hole golf course would still be the basis for the risk assessment and that all application scenarios would be based on the use of handheld equipment only because of the potential for damaging the turf with groundboom equipment. [Note: The agency would still anticipate minor use of groundboom equipment. However, a risk assessment would not be contingent on the use of this equipment unless a label restriction was added precluding the use of handheld equipment which is thought to be unlikely.] It is clear from the comments, however, that "Gowan cannot directly propose such an amendment to the Agency because all products which are actively sold for use on golf courses are registered by other companies." If no label restriction for tees and greens is added, EPA would not modify the groundboom and granular application risk assessments for bensulide, which are the basis for the preliminary risk assessment.

The golf course use based on the preliminary risk assessment can possibly be refined further if more reliable information is submitted that documents the annual frequency of use, actual application rates, as well as other pertinent exposure factors.

Since Gowan proposed an average acreage for greens and tees of approximately 7 acres in their comments on golf course uses, the Agency has included this scenario in its revised risk

assessment, and has incorporated the 21-day dermal and TTR studies to significantly refine these risks; many golf course uses are now not of concern, except for high exposure scenarios that involve the high pressure handwand and backpack sprayer.
For further details, refer to the revised human health risk assessment now available in the Public Docket and on the Agency's webpage

Other Professional Applications: Addressing the comments related to other professional applications (i.e., focused on turf uses) hinges upon refining the exposure factors related to the amount that can be treated in a day using specific types of handheld equipment. At issue is the use, by the Agency, of 5 acres per day treated area which is the standard Agency default value for turf applicator exposure scenarios. Gowan indicated "treatment of large areas by hand equipment would be inefficient and unprofitable because these [handheld] application techniques are slower than applications using mechanized equipment." Gowan also indicates that "we are told that one acre is a reasonable upper limit to assume for pushtype spreaders and backpack sprayers, and bellygrinders are almost never used by professional applicators." The risk picture would improve if one acre is used in the short-term assessment (i.e., application for more equipment types is allowable), but the risk picture does not significantly improve in the intermediate-term assessment using one acre per day (i.e., application equipment allowed did not change). Additionally, it has been recognized by the Agency for several years that the daily acres treated value of 5 acres per day is likely to be a conservative exposure factor. However, no reliable data have been submitted by Gowan, or any other registrant for that matter, that can be used to modify this value. As such, the Agency will use 5 acres per day in all turf assessments until more refined exposure factor data can be obtained. It should also be noted that preliminary Agency discussions with professional lawncare companies indicate that a one acre per day value is not a conservative estimate for short- and intermediate-term exposure assessment purposes.

Gowan is a member of the Outdoor Residential Exposure Task Force (ORETF) which has completed a use and usage survey for lawn care chemicals that is about to be submitted to the Agency. This dataset will be used by the Agency to refine the exposure factors for turf and lawncare chemicals once it has been submitted and reviewed.

Chemigation (agricultural) Applications: Addressing the comments related to chemigation and other agricultural applications hinges upon refining the exposure factors related to the amount that can be treated in a day using specific types of chemigation equipment and by refining the assumptions for the use of bulk packaging versus standard packaging in large-scale agricultural applications. Gowan commented that "to our knowledge, the largest area which has been treated with bensulide at one time is 80 acres, not 350 acres, and this occurred only in the desert Southwest. Elsewhere, the maximum area treated is thought to be 40 acres." As with the turf applicator scenario described above, the 350 acres per day exposure factor has been a standard default value that has been used by the Agency for several years. No reliable data have been submitted by Gowan, or any other registrant, that can be used to modify this value. As such, the Agency will use 350 acres per day in all chemigation assessments until more refined exposure factor data can be obtained. *In its revised risk assessment, the Agency has added a chemigation scenario for 40 acres per day, and have refined the risk picture for chemigation.*

The other comments from Gowan focused on the physical nature of chemigation applications and the available packaging. Gowan indicated that "Prefar 4-E herbicide is transported and distributed in bulk containers, not in standard 2.5 gallon jugs. This greatly reduces the exposure of pesticide handlers." Gowan also indicated that the lack of data does not warrant "using default assumptions.....which are known to be incorrect" to complete a chemigation assessment (i.e., the Agency used open pour liquid mixer/loader data from the Pesticide Handlers Exposure Database to complete the assessment). The Agency agrees with Gowan that the use of a closed chemigation application system would likely reduce exposures in the agricultural setting. However, the Agency has received no compelling evidence that the Gowan distribution system is indeed a closed system and that all bensulide users are equipped with a proper means to handle the bulk containers in a manner that ensures the integrity of the closed system. The Agency has also received no compelling evidence that all bensulide sales used in chemigation are bulk package sales (i.e., it may be necessary to restrict chemigation uses to bulk packaging coupled with closed systems). In order to refine this risk assessment, reliable information must be obtained that indicate how bensulide is marketed for agricultural applications (e.g., packaging) as well as data that indicate how bensulide is used on a daily basis in chemigation systems (e.g., maximum acres treated). The engineering aspects of the bulk packaging must also be submitted for review by the Agency so that a determination can be made concerning whether or not the system is truly a closed system. Additionally, the Agency will continue to use the open pour liquid exposure data that have been used as the basis for the chemigation risk assessment included in the preliminary risk assessment. The Agency agrees with Gowan that the use of this exposure assessment approach is not the most refined approach for quantifying chemigation exposures. However, the data used in this assessment are the best available for this scenario based on the Agency understanding of chemigation application methods and given the current exposure database. In order to refine the assessment, a chemical- and scenario-specific exposure study would need to completed by Gowan.

Comment 3

".....No use data were provided by the registrant concerning the actual application rates that are commonly used for bensulide." and ".....No use data were provided by the registrant concerning actual application rates...." (p. 41/par. 5 and p. 60/last par.)

We confirm that the Agency's assumptions about maximum application rates are correct. Many applications are made at the maximum application rates of 6 lb ai/acre for agricultural uses and 12.5 lb ai/acre for turf uses. Chemigation rates are normally 4 to 5 lb ai/acre. In practice, the minimum necessary application rates even under optimal conditions are approximately 60 percent of the maximum labeled rates.

EPA Response to Comment 3

The Agency will not alter the application rates used in the assessment as Gowan has concurred with the maximum values used in all assessments. The Agency commonly uses

maximum application rates for completing short- and intermediate-term risk assessments. If labels are altered and the maximum application rates are lowered, the Agency will modify the risk assessments accordingly.

Comment 4

(Table 7: Short-term Dermal Risks from Bensulide and Table 8: Intermediate-Term Dermal Risks from Bensulide): [various scenarios are addressed, based upon exposure calculations in Table 6]. (p. 47-51)

The Agency did not calculate acute dermal risks from bensulide but we believe that this is the most relevant measure of risk. The majority of mixers, loaders and applicators (agricultural workers) will not be exposed to bensulide more than one day per year. Some golf course superintendents may be exposed two days per year, with months in between applications, and a few may make three applications of bensulide.

Agricultural workers involved in chemigation may be exposed a few consecutive days per year but less than a week. Similarly, commercial lawncare personnel may apply bensulide over a few consecutive days within the very narrow window in early spring when the application of bensulide is feasible. These are the only two groups, in our opinion, for which the evaluation of short-term risk is appropriate. No user population is exposed to bensulide 7 or more consecutive days per year. It should also be noted that while short-term is normally defined as 7 days or less, the bensulide short-term NOAEL is derived from a developmental study involving consecutive days of exposure [cf. Table 3, p. 29].

The Agency's calculation of intermediate-term risk (Table 8) is therefore inappropriate and irrelevant to the assessment of actual occupational risk. We suggest that Table 8 be removed from the HED chapter.

Given our comments above regarding the treated areas, we wish to make the following observations on the Agency's calculation of short-term risk from various scenarios. We will only address maximum application rates.

<u>Mixing/Loading liquids for chemigation:</u> assuming the use of PPE (long pants and long-sleeved shirt) and engineering controls (chemical-resistant gloves), the Agency calculated an MOE of 87 for this activity. Using our maximum acreage assumption (80 vs. the Agency's 350), we calculate an MOE of 380. The use of bulk containers rather than the standard 2.5 gallon jugs constitutes a closed system and makes the chemigation of large areas the safest of all scenarios considered by the Agency.

<u>Other mixing/loading scenarios:</u> no comment is necessary since the Agency calculates adequate MOEs with or without PPE. We have no objection to adding PPE to the labels.

Applicator scenarios: no comment is necessary since the Agency calculated adequate MOEs without PPE.

Mixer/loader/applicator risk:

- Low pressure and High-pressure handwands and backpack sprayer: these scenarios would apply only to commercial applicators since the EC formulations are not available to homeowners. The Agency has assumed that up to 5 acres might be treated in a day. The Agency, by also calculating short-term, is also assuming that the applicator may treat this area for up to seven consecutive days, or 35 acres per week. (Please refer to the definition of short-term on page 29 of the chapter. The short-term NOAEL for bensulide was actually derived from 14 consecutive days of dosing in a developmental study.) We believe that these scenarios are unrealistic because they all involve a very inefficient use of manpower. The commercial applicators of whom we are aware use a truck-mounted nurse tank and a low-pressure, high volume handgun.

  Furthermore, the scenario using a high-pressure handwand is not realistic because: (1) high pressure is unnecessary to distribute the spray solution evenly and (2) high pressure favors drift, which is highly undesirable with most herbicides. We do no believe that bensulide is applied using a high-pressure handwand, and we would not object to a label restriction against this method of application.

- Low-pressure/high-volume handgun on turf: the Agency has calculated an adequate MOE for this scenario.

- Push-type granular spreader: the Agency calculated a minimum MOE of 37, assuming that 5 acres are treated. We believe, however, that an area as large as 5 acres will be treated by a tractor-drawn spreader, for which an adequate MOE has been calculated. We believe it is highly unlikely that an area larger than 1.5 acres would be treated using a push-type spreader, in which case the MOE would be greater than 100.

- "Bellygrinder": to our knowledge, bensulide is not applied by bellygrinders. It is our understanding that Green Light (the only company to whom this scenario applies) would no object to a label restriction against the use of bellygrinders.

EPA Response to Comment 4

The Agency does not concur with all Gowan comments presented above. Comments are addressed individually below along with the Agency's rationale for accepting or not accepting certain comments.

Exposure Duration Issue (Short- and Intermediate-Term Scenarios):

The Food Quality Protection Act requires that the Agency must now account for aggregate exposures and cumulative exposures if a common mode of toxicological action can be defined. This has required the Agency to develop a consistent system of nomenclature for completing risk assessments. The Agency has also considered the basic tenants of risk assessment by considering the probability of concurrent high (upper percentile) exposure events; this is reflected in the nomenclature that has been developed. The Agency believes that the predominant exposure pathway is through the diet at least in terms of total numbers of events and the frequency of those events, but not in terms of the magnitude of exposure. The Agency believes that the total number and frequency of nondietary exposures in the general population do not warrant combining conservative single day nondietary exposures in aggregate exposure calculations (i.e., values that would be used for any single day "acute" assessment and that are also used in current short-term and intermediate-term assessments) with acute dietary exposure estimates. The nomenclature developed by the Agency reflects this in that acute risk assessments are only calculated for dietary exposures (i.e., food and water). The Agency does, however, address single-day, high-end nondietary exposures routinely during the risk assessment process. For example, the short-term exposure interval is defined to include from single day up to seven days of consecutive exposure. For these risk assessment scenarios, the Agency used moderately conservative single day nondietary exposure values with the knowledge that the single day estimates are conservative but do not represent bounding estimate exposure values. If true bounding exposure values (based on label restrictions and no misuse) were calculated that would be appropriate for an acute scenario, the unit exposure values would be modified as current values, calculated using PHED, are somewhere between the geometric mean and the median of the dataset (see HED chapter for further explanation, pages 42 and 43), and the maximum area treated values for each application technique would likely be increased (e.g., the value used for groundboom agricultural application is 80 acres per day, this could likely be much higher for this technique).

It is the standard practice of the Agency to complete both short- and intermediate-term risk assessments for nondietary exposures in all occupational scenarios and also, in many instances, for residential post-application scenarios (depending upon the use and fate characteristics of the chemical). The Agency does not complete intermediate-term risk assessments for residential handlers as use practices generally are not repetitive over intervals from 1 week to several months (i.e., the definition of intermediate-term exposure scenario). [Note: An error is noted in the Agency risk assessment in that intermediate-term risk assessments were completed for residential handlers, these estimates will be removed in the revised risk assessment.] Given this premise, both short- and intermediate-term assessments were completed for bensulide. The definition of a short-term exposure scenario requires that from single-day up to seven days of consecutive exposures should be considered in this assessment. Bensulide use patterns certainly meet this criteria. The definition of an intermediate-term exposure scenario requires that from 1 week to several month exposures should be considered in the assessment. Obviously, the several month scenario would not be an accurate representation of bensulide use. However, the Agency does typically complete intermediate-term risk assessments for pre-plant/pre-emergent herbicides in agricultural settings and also for golf course chemicals where the

use pattern may dictate that individuals may be repeatedly exposed. The issue for the Agency is that reliable data are not available that can be used to characterize the use patterns for the chemical and the dynamics of the exposed population with such refinement (e.g., to ascertain how many days per year individual applicators actually use bensulide). Gowan provided an anecdotal discussion of this issue in their comments (e.g., "no user population is exposed to bensulide 7 or more consecutive days per year"). Further documentation of these assumptions would have to be provided in order for the Agency not to consider an intermediate-term risk assessment appropriate.

Mixing/loading liquids for chemigation: Two Gowan comments were presented pertaining to this issue. The first defines PPE (Personal Protective Equipment) as long pants and long-sleeved shirts and engineering controls as chemical resistant gloves. The standard approach used by the Agency for occupational risk assessment is that the baseline clothing scenario is long pants and long-sleeved shirts with no additional clothing or PPE. When the Agency adds a PPE, the mitigation items that are applied include a respirator, an additional layer of clothing, and chemical-resistant gloves. A single layer of clothing, as implied in the Gowan comments, has never been used to represent the use of PPE unless explicitly specified (usually it has been done in conjunction with gloves and a respirator). Likewise, gloves have always been considered to be PPE and never an engineering control. The other issue raised by Gowan is the acreage that can be treated using chemigation. This issue has already been addressed, see the Agency response above to Comment 2 above.

Other mixing/loading scenarios: Gowan offered no comment and agreed that "we have no objection to adding PPE to label." The Agency concurs that this is an appropriate modification of bensulide labels.

Applicator Scenarios: Gowan offered no comment as adequate MOEs were calculated without PPE. The Agency concurs.

Mixer/loader/applicator risk: Gowan offered a series of comments related to mixer/loader/applicator exposures in a manner specific to the equipment upon which the calculations were based. Each set of comments is addressed below individually.

- Low-pressure handwand, high-pressure handwand, and backpack sprayers: Gowan comments that "these scenarios would apply only to commercial applicators." Gowan also comments that "the Agency has assumed that up to 5 acres might be treated in a day" and that "the Agency, by also calculating short-term risk, is also assuming that the applicator may treat this area for up to seven consecutive days, or 35 acres per week." Gowan also indicates that the short-term NOAEL for bensulide was actually derived from 14 consecutive days of dosing in a developmental study" and the they "believe that these scenarios are unrealistic because they involve a very inefficient use of manpower." The Agency notes that exposure assessments for these equipment types were completed only for occupational applicators. When short-term risk assessments are completed by the

Agency, any exposure scenario where the anticipated frequency is from 1 to 7 days is included. Any scenario that fits the criteria (i.e., exposures ranging from single day events to consecutive events over a 7 day interval) is treated by the Agency as a short-term assessment for nondietary exposures (see explanation above for not treating single day exposures as acute -- revisions to exposure factors and probability associated with also combining high-end dietary exposures). Bensulide fits this criteria as evidenced in comments from Gowan that indicate that they believe that most applicators will use bensulide from 1 to 3 times per year. They also add that a "a few [golf course superintendents] may make three applications of bensulide." In fact, the Agency has not assumed that bensulide applicators will treat 35 acres in one week using handheld equipment. The Agency has assumed that an applicator might treat up to 5 acres on a single day, which based on current Agency policy, would be treated as a short-term exposure scenario. The efficiency/manpower issue has already been addressed, see the Agency response above to Gowan comment 2 in section 2.B.ii for further information.

- High-Pressure Handwands: Gowan indicates that "the scenario using a high-pressure handwand is not realistic because: (1) high pressure is unnecessary to distribute the spray solution evenly and (2) high pressure favors drift, which is highly undesirable with most herbicides." Gowan also indicates that "we would not object to a label restriction against this method of application." The Agency agrees in theory with the Gowan comments. However, bensulide is labeled on a variety of non-food crops and residential targets including turf, deciduous trees, herbaceous plants, and groundcovers. When the Agency develops risk assessments for these kinds of applications and the available labeling does not preclude certain application methods (e.g., labels generally indicate hand application or some other non-specific statement), a suite of application techniques is automatically selected to address these scenarios and that suite of application methods includes high-pressure handwands, backpack sprayers, and low-pressure handwands. The Agency concurs with Gowan restricting high-pressure handwand use from the label. The Agency also notes that if such a restriction is not added to bensulide labeling that the high-pressure handwand scenario would remain in the assessment because bensulide can be applied to ornamental plants as well as turf, and the use of high-pressure devices on ornamentals is considered plausible by the Agency.

- Low Pressure/high-volume handgun on turf: Gowan indicated that the Agency calculated adequate MOEs for this scenario and the Agency concurs.

- Push-type Granular Spreader: Gowan comments that the Agency "calculated a minimum MOE of 37, assuming that 5 acres will be treated" and "that an area as large as 5 acres will be treated by a tractor-drawn spreader, for which an adequate MOE has been calculated." Gowan also indicates "it is highly unlikely that an area larger than 1.5 acres would be treated using a push-type spreader." This issue has already been addressed above in the Agency response to Gowan comment 2, see section 2.B.ii above for further information. It should be noted that in Gowan comment 2, the maximum acreage believed

to be plausible was 1 acre per day and not 1.5 acres for push-type granular spreaders. Irregardless, the referenced comment still applies.

- "Bellygrinder": Gowan indicates that "bensulide is not applied by bellygrinders" and "it is our understanding that Green Light (the only company to whom this scenario applies) would not object to a label restriction against the use of bellygrinders." When the Agency develops risk assessments for these kinds of applications and the available labeling does not preclude certain application methods (e.g., labels generally indicate hand application or some other non-specific statement), a suite of application techniques is automatically selected to address these scenarios and that suite of application methods includes push-type spreaders and bellygrinders. The Agency concurs with Gowan restricting bellygrinder use from the label. The Agency also notes that if such a restriction is not added to bensulide labeling that the bellygrinder scenario would remain in the assessment because bensulide applications by lawncare companies and in the residential setting are considered plausible by the Agency.

Comment 5

".....further information pertaining to the use of bensulide and any cultural practices associated with the crops in question should be provided in order for [the Agency] to assess any scenarios where there is exposure potential....." (p. 59/par. 1, postapplication and assumptions)

We appreciate the opportunity to offer the following clarifications:

Bensulide is not applied aerially. We acknowledge that this is not stated on the label, and we would be willing to amend the label to clarify this point.

The agricultural use of bensulide entails application before planting, or after planting but before the crop emerges from the soil.

Bensulide is not used on sod farms.

EPA Response to Comment 5

The Agency concurs with Gowan's comments and based the preliminary risk assessment on this information, anticipating the confirmation included in the above comment. The Agency did not include an aerial application scenario in the preliminary risk assessment. Also, EPA acknowledged that bensulide is a pre-plant/pre-emergent product as it did not complete post-application exposure analyses for the agricultural uses of bensulide (e.g., no sod farm or typical agricultural scenarios were assessed -- such as scouting).

Comment 6

"The Agency evaluated bensulide use patterns in the ornamental and residential marketplaces and determined that there are likely post-application exposures....." (p. 59/par. 2, exposure scenarios)

The discussion above regarding use only on golf course greens is applicable here. The treated area to which golfers are exposed is much smaller that what the Agency has assumed, and dermal exposure will be correspondingly reduced.

EPA Response to Comment 6

This issue has already been partially addressed above in EPA's response to Gowan Comment 2 above. It should be noted that this response applies only to golf course workers and for golfer exposure. If a golf course use restriction to tees and greens is added to bensulide labeling, the Agency concurs that postapplication exposures would be reduced.

With the recent submission of the turf transferable residue study, post-application exposures to golfers have been revised. This study has been incorporated into the revised human health risk assessment that is now available in Public Docket.

Comment 7

"Due to a lack of chemical-specific transferable residue data (TR), a surrogate approach has been used.....Available residues on application day are assumed to be 20 percent of the application rate and the residues are assumed to decline as a rate of 10 percent per day." (p. 60/par. 5, transferable residue data)

It is true that data specific to bensulide do not currently exist. However, a dislodgeable residue dissipation study on turf is scheduled to begin this month. The study duration is only 35 days, so a report is expected to be available later that year. (This study is not due under the Outdoor Residential DCI until October, 1999.) We will of course submit this information to the Agency as soon as possible in order to permit a more precise exposure and risk determination.

We believe that our study will demonstrate initial residue levels much below those which would normally be predicted because of the requirement that all applications on turf must be immediately watered into the soil in order for bensulide to be herbicidally effective. Irrigation involves either washing the EC formulation off the surface of the grass leaves, or disintegrating a granular formulation and washing any associated dust into the soil. We expect that initial residues after irrigation will be at least an order of magnitude below the Agency's estimate of 20 percent applied residues.

It was not clear from the Agency discussion whether the assumption of a 10 percent reduction per day in the residues involved first-order or zero-order kinetics. However, Tables 11 and 12 (pp. 63-66) show that the Agency assumed first-order kinetics and carries out some calculations past 60 days.

If the Agency had assumed zero-order kinetics rather than first-order kinetics, all residues would be gone after 10 days. It is our belief that zero-order kinetics more accurately model actual residues on turf-grass than first-order residues. Our reason is very simple, grass is mowed.

In golf courses, bentgrass greens are normally kept very short, 1/8 to 3/16 inch high. These greens are normally mowed every single day during the seasons when the grass is actively growing. Golf course tees are similarly cared for, and the grass is only slightly higher, 1/4 to 3/8 inch. The cut grass is bagged and removed from the premises because short, valuable, highly visible, high-traffic, highly ornamental grass is not compatible with the practice of mulching during mowing. The treated leaf mass is therefore rapidly removed from these areas and is soon completely replaced by untreated grass. We do not believe that there is any reasonable expectation that untreated grass will contain significant transferable surface residues.

In other areas such as home lawns the rate of residue decline is expected to be somewhat slower since the grass is kept higher, and therefore a longer time is required for all of the treated grass to grow out.

EPA Response to Comment 7

In lieu of chemical- and site-specific data, EPA often uses Tier 1 type screening models to assess nondietary exposures. The defaults that have been used by the Agency for several years in a variety of assessments for modeling transferable residue concentrations over time have been the standard defaults that were used in the bensulide assessment (i.e., 20 percent of rate is transferable and 10 percent dissipation per day). These values were derived based on the best professional judgement of Agency scientists after review of a variety of dislodgeable and transferable residue dissipation data. These values are expected to be conservative.

The Agency does not concur with Gowan that there is ample evidence to modify the default transferable residue value inputs for several reasons. The characteristics of bensulide use on turf and the persistence of the molecule do not indicate that reducing the factors is a prudent step without chemical-specific data. The label requirements for bensulide require that the material be watered in which would likely cause it to reside in the thatch layer. Hence it is likely that bensulide residue levels would not be greatly effected by mowing events. Additionally, the environmental fate data available for bensulide indicate that the molecule is extremely persistent in various media compared to other organophosphate compounds. Half-lives, as measured via soil photolysis, aqueous photolysis, and hydrolysis are all greater than 200 days which indicates persistence. The persistence of bensulide coupled with the watering-in requirement offer the potential that bensulide might reside in the thatch layer of turf over long intervals and might be a persistent contributor to exposure.

The Agency has since revised the post-application risk assessment to incorporate data from the turf transferable residue (TTR) study. This study and the revised risk 21-day dermal toxicity study has contributed to significant revisions to post-application exposure assessment.

Comment 8

"Due to a lack of scenario-specific exposure data, the Agency has calculated unit exposure values....." (p. 61/par. 1 exposure data)

Gowan was not able to reconstruct the Agency's calculations. We request a copy of the detailed calculations.

The Agency is aware that Gowan is a member of the industry Outdoor Residential Exposure Task Force. We wish to bring to your attention an update on the progress of ORETF which was presented to the Scientific Advisory Panel on March 25, 1998. The following statements were made:

> "....The ORETF initiated its research program almost 2 years prior to the enactment of FQPA. With the advent of FQPA, the overall scope and complexity of the research program has markedly increased, resulting in the need for quantitative exposure data on an age- and activity-specific basis. The ORETF has completed the field phase for multiple studies to measure the exposure to homeowners applying different formulation types and using various application equipment. Similar studies have also been completed for professional lawncare operators, although not covered under FQPA. However, the ORETF is now set to embark on the most difficult of its objectives. The question is how much potential exposure exists for people of various age groups who enter a lawn after it has been treated with a pesticide, the answer to which is predicated upon extensive knowledge of tho is entering the lawn, how much time is spent on the lawn, how much bodily contact they have with the lawn, and so forth. Thus, the question is extremely complex and a number of scientific efforts are underway in EPA, academia, and industry. The ORETF is in the process of conducting its own survey over the next 15 months to characterize the activity patterns of specific age groups on turf, at an estimated cost of $1 million.
>
> "..... The ORETF has committed a vast amount of monetary and temporal resources to address the issues of exposure from treated lawns, but needs the time to produce the data. Producing the data for compounds that have been prematurely forced out of existence makes no sense.
>
> "..... In summary, it is our scientific judgment that the current default assumptions greatly overestimate exposure and that previous evaluations have not indicated that an imminent danger exists from outdoor exposure to pesticides in a residential setting.....Therefore, all we are asking of the SAP and the various regulatory agencies is to allow adequate time to generate accurate and reliable exposure data that will provide a sound scientific basis for making informed risk judgements."

EPA Response to Comment 8

The Agency acknowledges these comments and applauds the progress of the Outdoor Residential Exposure Task Force to date. However, in lieu of reliable, existing data, EPA must ensure that exposures related to the use of turf chemicals are regulated in such a manner that is protective of human health. Given this consideration, the default exposure factors used in the current risk assessment for bensulide will remain until additional ORETF data (or other data) become available with which to refine the exposure factors. The Agency will consider other pertinent data as these data become available.

The Agency has received and incorporated the turf transferable residue study into the revised human health risk assessment.

Comment 9

"The calculations presented in this section serve as the basis for both the short-term and intermediate-term post-application risk assessments...." (p. 61/par. 2)

Given the discussion above regarding the p. 60, par. 5, Gowan does not believe that intermediate-term risk assessments are appropriate. We believe instead that acute and short-term risk assessments are appropriate for evaluating post-application risks. In as much as the short-term NOAEL is 11 times higher than the intermediate-term NOAEL, calculations regarding risk will differ by an order of magnitude, depending on the assumed length of exposure.

"Short-term" is generally defined as 1 to 7 days. Again please note, however, that the short-term NOAEL for bensulide is derived from 14 consecutive days of exposure (days 6 - 20 in a rat developmental toxicity study; cf. pp. 14 and 29). Therefore we consider the short-term NOAEL to be appropriate for all exposures up through two weeks.

EPA Response to Comment 9

The exposure duration issue has been previously addressed by the Agency in its response to Gowan Comment 4. Additional discussion is also provided in the Agency responses to Gowan Comments 1 and 2. The rationale that has been used by the Agency in those responses also applies here regardless of whether it is for handler or for postapplication exposure scenarios. EPA's response to Gowan Comment 7 should also be considered as the environmental fate characteristics of bensulide indicate that it may be persistent. Therefore, intermediate-term exposure assessments become pertinent in lieu of more refined data.

Comment 10

"Dermal risks for handlers were assessed using the short-term and intermediate-term toxicological endpoints." (p. 68/last par.)

The acute NOAEL for bensulide is 15 mg/kg. The short-term (1 to 7 days) NOAEL for bensulide is 5.5 mg/kg/day, whereas the intermediate-term (1 week to several months) NOAEL is defined as

0.5 mg/kg/day [cf. p. 29]. We noted above acute and short-term endpoints are relevant to evaluating risk scenarios for handlers. However, it is not appropriate to conduct an intermediate-term toxicological assessment with bensulide since intermediate-term exposure to handlers never occurs.

The vast majority of agricultural applicators are exposed only one day per year. A few individuals involved in chemigation application on large commercial vegetable farms may be exposed two or three days per year. No agricultural applicator is exposed seven days per year.

Similarly, most grounds keepers on golf courses are exposed only one day per year. Some are exposed two days per year, with some months between exposures, and a few may apply bensulide up to three times per year. We do not believe that any such individual is exposed to two consecutive days of exposure.

If bensulide is still used by professional lawncare applicators, these individuals could be exposed for a few consecutive days per year during a short period in the early spring. Please refer to our discussion above concerning the HED chapter p. 41, par. 4 concerning various exposure scenarios. Some of the exposure equipment scenarios considered by the Agency are highly unlikely. It is our understanding that a label restriction against some of these scenarios would have no commercial impact and would be acceptable to the affected registrants.

EPA Response to Comment 10

The exposure duration issue has been previously addressed by the Agency in its response to Gowan Comment 4 above. Additional discussion is also provided in the Agency responses to Gowan Comments 1 and 2. The rationale that has been used by the Agency in those responses also applies here regardless of whether it is for handler or for post-application exposure scenarios.

Comment 11

"On turf in occupational settings, at an application rate of 12.5 pounds active ingredient per acre, MOEs did not equal or exceed 100 for activities on turf....." (p. 71/par. 5 intermediate term occupational postapplication exposure)

We believe that three standard assumptions which the Agency has used are not applicable in this case due to the properties or use patterns of bensulide. These assumptions are as follows:

1. The Agency has assumed that residues on turf dissipate as the rate of 10 percent per day [cf. RED p. 60, par. 5]. We believe that initial residues will be lower than what the Agency has assumed because bensulide must be watered in soon after application in order to be effective.

2. Secondly, as we noted earlier, we believe that residues on turf will not be present longer than about a week simply because the grass is mowed. On golf greens and tees in particular, mowing

occurs quite frequently and grass clippings are removed from the site. This will limit postapplication exposure on golf courses to short-term exposure; an intermediate-term exposure risk assessment, in our opinion is not appropriate. We expect our turf foliar residue dissipation study to demonstrate this to the Agency.

3. Thirdly, we believe that the timing of applications to home lawns will generally preclude significant dermal exposure. The only bensulide product which can be purchased and applied by homeowners is Green Light Betasan 3.6 granules EPA REG No. 869-212. Its label states,

> "Applications of Betasan must precede emergence of weeds from the soil. Crabgrass will emerge from the soil from four to six weeks before it is visible above lawn sod. If weeds are visible above the soil, it is too late to apply Betasan."

In practice, this product is almost always applied very early in the spring before the lawn emerges from winter dormancy. At this time the weather is generally cold and the lawn is unattractive and uninviting for close contact. Direct contact of skin, except for hands, with the lawn at this time of year would be unusual.

The Green Light label also permits a second application during late summer or early fall. Lawns would be actively growing during this period and our comments would not apply. We understand that use at such time is extremely small, however, compared to use during late winter or early spring when lawns are dormant.

In any event as we have noted, a turf dislodgeable residue study with bensulide is scheduled to begin on May 12, 1998. Results should be available well before the Agency expects to conduct a cumulative risk assessment of the organophosphate pesticides. The study will permit a more accurate exposure assessment. As we noted above, we believe that it would be inappropriate for the Agency to immediately impose any risk mitigation measures based upon conclusions derived from default assumptions when significant new information will become available shortly. We therefore respectfully request that final decisions regarding risk mitigation be deferred until these data are available.

EPA Response to Comment 11

With regard to parts 1 and 2 of this comment, the Agency refers to its response to Comment 7 above. The kinetics issue and the persistence/availability issue are both addressed in that response. Two issues are critical to responding to part 3 of the comment; the Agency refers to its response to Gowan Comments 7 and 8 above as the issues raised in those comments are similar to those raised here. Additionally, like the lack of turf dislodgeable data, there is also a lack of population-based activity pattern data that links exposure events and chemical use patterns. The lack of reliable data to assess appropriate activity patterns related to bensulide use provides justification for completing the postapplication exposure assessment.

(b) Gowan's comments from a letter dated October 8, 1998, sent to the public docket.

Comment 1

"Handler exposure assessments are completed by the EPA using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure...." (p. 42)

The Agency's calculations are only as good as the default assumptions used in the calculations. In the table on page 44 of the [HED chapter], for example, the Agency estimated baseline exposure to bensulide (Prefar 4-E, a 4 lb ai/gallon EC formulation) from chemigation application. The Agency used a baseline dermal unit exposure of 2.9 mg/lb ai and derived a daily dermal exposure of 6,090 mg ai/day. This value was used to calculate short-term dermal risks (page 47), and a baseline dermal MOE of less than 1 was derived.

By comparison, a study with a very similar organophosphate product, Lorsban (chlorpyrifos) 4E, has been evaluated previously by the Agency (MRID 42974501). This study was submitted by Dow Agro and has been purchased by the Agricultural Reentry Task Force, of which Gowan Company is a member. In this study, the mean dose of chlorpyrifos which was actually absorbed by mixer/loaders was 0.0078 mg/kg/day, or 0.55 mg/day, assuming a 70 kg worker. Therefore, actual measured exposure using a formulation very similar to Prefar 4-E was over 11,000 times - four orders of magnitude - lower than the Agency's baseline calculation. This is probably due to several factors including the use of personal protective equipment (PPE) and the Agency's acknowledged overestimation of the rate of dermal absorption of bensulide (cf. p. 26 of the chapter). Gowan's rebuttal letter of May 1, 1998 addressed two other factors: an overestimation of the acreage treated and the fact that bulk containers, rather than 2.5 gallon jugs, are used in chemigation applications. In fact, bulk containers constitute closed systems, so it is questionable whether "mixer/loaders" for chemigation application even exist.

We believe that similar overestimations of exposure permeate the Agency's exposure evaluations of other scenarios. The Agency is well aware that the crop protection industry for years has been committed to the development of exposure information regarding agricultural and residential use through the ARTF and ORETF. We believe that any precipitous action by the Agency toward "remediation" of hazards which have not been demonstrated to actually exist would be entirely unwarranted. Risk mitigation should occur after risk assessment, not before it.

EPA Response to Comment 1

The issues presented in this comment are essentially the same as those presented in various aspects of the May 1, 1998 rebuttal letter that is addressed above. It should also be pointed out that no chemical-specific exposure or toxicology data were submitted to bridge bensulide exposures with the referenced chlorpyrifos study. Additionally, the comments by Gowan are not understood by the Agency as the ARTF is focusing only on postapplication exposure issues (e.g.,

agricultural harvesters and scouts) and the referenced study would not have been used by the ARTF as the study quantifies exposure to pesticide handlers (e.g., Gowan reports mixer/loader exposures and not postapplication exposures from the study). The issue of data compensation and transferability of the data are also not addressed by Gowan. To date, no exposure data have been submitted to the Agency by the ARTF in order to adequately address compensation issues.

The Agency acknowledges the comment and pertaining to risk mitigation applauds the progress of the Outdoor Residential Exposure Task Force to date. However, in lieu of reliable, existing data, the Agency must ensure that exposures related to the use of turf chemicals are regulated in such a manner that is protective of human health. Given this consideration, the default exposure factors used in the current risk assessment for bensulide will remain until additional ORETF data (or other data) become available with which to refine the exposure factors. The Agency will consider other pertinent data as these data become available. *The Agency has incorporated the recently submitted turf transferable residue study into the revised risk assessment – this data has been used in place of some of the Agency's assumptions regarding post-application exposure.*

Comment 2

"...Additionally, when applied pre-plant in agricultural settings, bensulide is soil incorporated. This is generally well before the plants are mature which minimizes the potential for post-application exposure due to contact with treated foliage." (p. 59/par. 1)

The Agency's observation that application is well before the plants are mature is entirely correct. In fact, it is before the seedlings have emerged from the soil. We emphasize again that agricultural bensulide is applied only to bare ground. Since 1996, the labels for Prefar 4-E Herbicide, Prefar 6-E Herbicide and Betasan Technical have had specific restrictions against foliar application to food crops.

EPA Response to Comment 2

The Agency concurs with this comment but does not understand the criticism because the preliminary risk assessment did not include agricultural post-application exposure scenarios as the Agency recognized that agricultural post-application exposures would be minimal or nonexistent. In fact, the only occupational post-application exposures that were calculated for bensulide were for turf management workers. In this scenario, the exposed personnel were expected to spend 4 hours per day in exposure-related activities. The Agency did, however, ask for further documentation from Gowan Company to further document the cultural practices in agricultural settings that is not provided in either rebuttal letter to the Agency.

Comment 3

"The following specific assumptions and factors were used in order to complete the exposure assessment:

> MOEs for adults in the occupational scenarios (e.g., turf management) were calculated using the intermediate-term endpoint, since the intermediate exposure scenario is likely based on the environmental fate characteristics of bensulide. The EFED One-Liner Database was checked and the t½ is 220 days (solar days) based on soil photolysis; 200 days for aqueous photolysis; and 220 to 230 days for hydrolysis.
>
> Due to a lack of chemical-specific transferable residue data (TR), a surrogate approach has been used to predict transferable residue levels over time as specified in the residential SOPs. Available residues on application day are assumed to be 20 percent of the application rate and the residues are assumed to decline at a rate of 10 percent per day." (p. 60)

The half-lives for the photolysis and hydrolysis are correct. However, the primary route of disappearance is through soil dissipation. The EFED draft chapter assumed a half-life for bensulide in soil of approximately a year. This was derived from a laboratory soil metabolism study while ignoring eleven field dissipation studies which show a median half-life of 34 days. Gowan addressed this point in detail in our rebuttal of March 19, 1998. In summary, we believe that the Agency has overestimated the half-life of bensulide in soil by an order of magnitude. This has a profound bearing on the conclusion that an intermediate-term endpoint should be evaluated for the human health effects from bensulide.

Regarding use of a default value of 20% of the application rate for the amount of dislodgeable foliar residue initially present, TRO, we note that values in the literature range from 1% to 11%.

We believe that the Agency's residential SOPs for dissipation, which were used here, are not specifically applicable to bensulide. Bensulide must always be either mechanically incorporated or watered in to be herbicidally effective. Watering in must occur soon after application, and in practice this generally occurs immediately after application. Gowan addressed this subject in detail in our March, 1998 response to the EFED draft chapter. Watering bensulide into turf transfers a substantial portion of the residues, if not all, from foliar surfaces to the soil, where bensulide must be situated in order to be herbicidally active. Efficacy data and long experience show this to be true.

We believe that watering in introduces a step change in foliar residues; i.e., the initial transferable residues on turf will be substantially reduced by the act of watering, down to level much below that which would be predicted by first-order kinetics. Therefore, we believe that the standard assumption of dissipation by first-order kinetics is not applicable here. This means, for example, that the first order equation for transferable residues at time (t) (page 62 of the HED chapter) cannot be used in this instance.

$$Tr_t = TR_0 * (1-D)^t$$

[where D = fraction of the residue that dissipates each day]

A step change could be indicated as:

$$TR_{\text{after watering}} = R * TR_{\text{before watering}}$$

[where R = reduction of residues by watering in.]

That is, a fraction of the residues (which Gowan is determining empirically) is immediately removed by watering in.

Furthermore, in turf, zero-order kinetics are expected to prevail. The difference between first-order and zero-order dissipation at time (t) can be expressed as

$$(1-D)^t \text{ versus } (1-D) * t$$

With first-order kinetics it is not possible to theoretically reach zero; with zero-order kinetics and using the Agency's assumption of 10% reduction per day, zero residues would be reached in 10 days. Our belief is based upon the nature of turf grass growth and maintenance.

After bensulide is watered into soil below the thatch layer, any remaining transferable residues would adhere to the grass foliage. New grass foliar tissue is generated at the base of the leaf and will not have been in contact with bensulide. The grass leaf tissue with transferable residues will grow continually higher and eventually be removed by mowing. The residue-containing leaf tissue is therfore rapidly replaced by new growth, and residues should rapidly reach nondetectable levels. The situation is described by zero-order kinetics. In some situations involving high-maintenance turf (e.g., on golf greens), the grass is kept very short and may be mowed once or even twice per day. The mowed foliage is removed from the premises. Therefore it is expected that all dislodgeable residues would be removed in a period of a very few days.

Gowan Company has committed to determine TR0 (before watering and after watering) and Trt empirically rather than by calculation. The field work was conducted in the summer of 1998 but analytical results are not yet available. These are expected shortly. In the meantime, we believe that it would be inappropriate for the Agency to take "remedial" action based upon theoretical calculations and default assumptions rather than reliable data which will soon be available.

EPA Response to Comment 3

The Agency responded to similar comments above -- developed in response to Gowan Comments 7 and 8 from the May, 1998 letter. Additionally, the Agency acknowledges these comments and applauds the progress of the Outdoor Residential Exposure Task Force to date. However, in lieu of reliable, existing data, the Agency must ensure that exposures related to the use of turf chemicals are regulated in such a manner that is protective of human health. *The Agency has received and incorporated data from the recently submitted turf transferable residue study into the revised risk assessment.*

Comment 4

"Due to a lack of scenario-specific exposure data, [the Agency] has calculated unit exposure values for adults using surrogate transfer coefficients..." (p. 61/par. 1)

Scenario-specific exposure data are being developed by the Outdoor Residential Exposure Task Force. Gowan has been a member of the task force since its inception in 1995. Interim data are expected to be available soon. We propose that EPA delay further analyses using default assumptions and wait until actual data are available.

EPA Response to Comment 4

The Agency acknowledges these comments and applauds the progress of the Outdoor Residential Exposure Task Force to date. However, in lieu of reliable, existing data, the Agency must ensure that exposures related to the use of turf chemicals are regulated in such a manner that is protective of human health. Given this consideration, the default exposure factors used in the current risk assessment for bensulide will remain until additional ORETF data (or other data) become available with which to refine the exposure factors. The Agency will consider other pertinent data as these data become available -- it also should be noted that the ORETF exposure-related data are not expected in final form for a substantial amount of time as several basic research needs have been identified in this area. *However, the Agency has incorporated data from the recently submitted turf transferable residue study into the revised risk assessment.*

Comment 5

"The calculations presented in this section serve as the basis for both the short-term and intermediate-term postapplication risk assessments. No chemical-specific post-application human reentry or transferable residue data have been submitted to date in support of the reregistration of bensulide...." (p. 61, par. 2)

We reiterate our belief that there will be no intermediate-term post-application exposure from turf. This will soon be determined empirically, however. It is true that no transferable residue data for bensulide have yet been submitted. These data were required by October, 1999 in the Agency amended data call-in of February 1998. Gowan expects to submit this information to the Agency almost a year early, however.

EPA Response to Comment 5

The Agency reiterates its position that there is a potential for intermediate-term exposure from turf given the apparent environmental fate characteristics of bensulide and given the lack of chemical-specific data. *However, the turf transferable residue (TTR) study has been received and incorporated into the revised risk assessment.*

B. Response to Comments on the Preliminary Environmental and Ecological Effects Risk Assessment (EFED Chapter)

1. Comments from Gowan Company

Comment: To fulfill outstanding guideline requirements, the following studies are being conducted or the final report is in preparation: fish early life-stage study, freshwater invertebrate life-cycle study, seedling emergence, vegetative vigor, and aquatic plant testing with 5 species. A new avian reproduction study has already been submitted.

EPA Response: The Agency has completed review of the new avian reproduction study. The other studies will be reviewed once they are submitted, at which time the status of data requirements will be updated.

Comment: Gowan asks that the Agency waive the requirement to submit a core study on the acute toxicity of bensulide on freshwater invertebrates.

EPA Response: The Agency waives the data requirement for a new acute freshwater invertebrate study (72-2a). The study that was conducted to fulfill this guideline was supplemental due to unacceptably low levels of dissolved oxygen (DO) in the four highest test concentrations. The DO level was normal in the control (98%) and decreased as the exposure concentration increased, reaching a maximum of 27% at the highest test concentration. Any adverse effect caused by the low DO would increase the slope of the dose-response curve and decrease the value of the LC_{50}. This study, if anything, probably underestimated the LC_{50} of bensulide to the waterflea, thus use of this value in the risk assessment is likely to overestimate rather than underestimate risk. The Agency therefore does not require a new study if the registrant is willing to accept the LC_{50} value of 0.58 mg ai/L.

Comment: Gowan offers to submit a report of interim results of a new field dissipation study which is currently being conducted. They claim that the results will support their claim that the half-life value used by EPA in our preliminary risk assessment is an "outlier."

EPA Response: The Agency will wait and review the entire study once it is complete. It would not be an effective use of our time to review interim results of this study. Even if we did, the results would not likely have much, if any, impact on our conclusions. As stated in a previous rebuttal, a field dissipation half-life is not used in our models for water exposure. However, information from an acceptable field dissipation study would be considered in our risk characterization.

2. Comments from A Weed Science Advisor & EPA's Response

A Mr. Carl E. Bell, the Weed Science Advisor in the Imperial Valley for southeastern California, submitted comments concerning the risk of bensulide when used on vegetables in the desert southwest. Mr. Bell claims that the draft EFED chapter exaggerates some of the risks of bensulide because regional characteristics of the desert growing region limits exposure to nontarget plants and animals. EPA generally agrees with Mr. Bell's comments. In fact, the risk characterization for use on vegetables currently states that:

> "Because of the above factors [that limit exposure in nontarget organisms], the use of bensulide is not expected to pose a serious risk to terrestrial organisms, including mammals, due to acute effects."

To clarify this statement, the term "terrestrial organisms" will be changed to "terrestrial plants and animals." In addition, the qualitative risk assessment for bees currently states:

> "Bensulide is applied to bare ground (vegetable uses) or to turf. These uses are expected to result in little exposure to flowering plants, thus exposure to bees is expected to be minimal."

The only risk identified in the preliminary risk assessment from use on vegetables, other than to threatened and endangered species, is chronic risk to birds and mammals. As explained in the chapter, the Agency concludes that there is a high risk of chronic effects, despite factors that may limit exposure, because the toxicity and risk quotients are extremely high, and because bensulide is highly persistent in the environment. Furthermore, we do not agree with Mr. Bell's statement that the only species of birds and mammals that will occur in bare vegetable fields are pest species. Species such as the horned lark are part of the native fauna and deserve protection. Small nocturnal rodents are expected to quite numerous in these field, especially along the borders.

The Agency appreciates the information that Mr. Bell provided on the selectivity of bensulide. Unfortunately, the Agency has not yet received data from an acceptable phytotoxicity studies that shows the toxicity of bensulide to nontarget terrestrial plants. Gowan Company has informed us that these studies have been completed and will be submitted to the Agency soon. Once these data are received, the Agency will reevaluate the risk to nontarget plants, and will take your comments into account at that time. In the meantime, the Agency must assume a high risk to terrestrial plants.

EPA agrees that there is little risk to aquatic invertebrates from the use of bensulide on vegetables in the desert southwest due to the limited potential for exposure. The draft EFED chapter already addressed Mr. Bell's concern in the risk characterization section. In this section, the Agency concludes that "except for endangered species, risk to aquatic ecosystems in these areas [Arizona and southern California] is not a major concern." The Agency assessment for threatened and endangered (T&E) species is more conservative than that for other species because of the greater importance in protecting these species. The risk that bensulide could harm aquatic T&E species cannot be discounted because of the potential for chronic effects. As with

terrestrial plants, chronic risk to aquatic organisms must be assumed until the Agency receives adequate data on chronic toxicity to perform a risk assessment. EPA agrees with Mr. Bell that there is little potential for significant residues of bensulide to reach distant aquatic ecosystems such as the Salton Sea. However, there is the *potential* for T&E species to occur close to the use areas, even within man-made drainage canals. In writing risk assessments, the Agency does not attempt to identify which, if any, T&E species occur within the use areas.

EPA agrees that the discussion on risk to threatened and endangered (T&E) species somewhat overstates the risk to these species. In the section under the heading **Endangered Species**, the term "unacceptable risk" will be changed to simply "risk." In the first sentence of this section, a qualifier will be added stating that species may be at risk "if they occur in or near the use area." For aquatic species, the following qualifier will be added:

> "In the Southwest desert region, risk to T&E aquatic species is not expected unless the species occur in drainage ditches or canals adjacent to the application areas."

As stated above, the Agency does not identify which, if any, T&E species would be exposed by the registered use when writing the risk assessment; it only identifies groups of species that might be harmed *if they are present*. The risk assessment does not restrict the use of bensulide to protect T&E species.

Part II: Non-Chemical-Specific Comments and Responses

Non-chemical-specific comments were received from: American Crop Protection Association; Idaho Farm Bureau Federation; National Coalition Against the Misuse of Pesticides (NCAMP); National Cotton Council; Learning Disabilities Association; Fish and Wildlife Service, Division of Environmental Contaminants; Texas Agricultural Extension Service; Natural Resources Defense Council (NRDC); the Grocery Manufacturers of America, Michigan Agricultural Cooperative Marketing Association; U.S. Apple Association; Southern Professional Fruit Workers Conference (held at Clemson University); and 16 individuals, 13 of whom identified themselves as pest control operators (PCOs) or otherwise associated with the professional pest control industry.

Because there are several recurring issues in the comments that were submitted, we have chosen to divide our responses into two sub-sections. In order to avoid repetition, sub-section A deals with comments that are closely related and were repeated in more than one of the submissions, and with comments that are testimonial in nature. Sub-section B responds to those comments that are unique to each submission and refers the reader to the appropriate common responses in sub-section A.

A. EPA Responses to Recurring Issues in the Non-Chemical-Specific Comments

1. Comments Related to Common Mechanism of Toxicity

Comments: The Idaho Farm Bureau Federation felt that the criteria defining all organophosphate pesticides as having a common mechanism of toxicity are too broad, and that EPA should develop appropriate criteria for common mechanism. Other commentors, the NRDC and NCAMP, questioned why EPA has not considered a common mechanism of toxicity in these first nine OP risk assessments.

Response: With respect to developing criteria, EPA is required under FQPA to consider available information on the effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity. EPA believes that the organophosphate pesticides should be considered to operate via at least one common mechanism of toxicity--cholinesterase inhibition, unless and until the Agency receives data demonstrating otherwise.

In the Federal Register of August 6, 1998 (63 FR 42031 (FRL-5797-9), EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides." The guidance document describes the approach that EPA proposes to use for identifying and categorizing pesticide chemicals that have a common mechanism of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. The 60-day comment period ended October 8, 1998. The revised guidance was issued in February, 1999. In developing this document, the Agency solicited advice from the FIFRA Scientific Advisory Panel (SAP) in February 1997; a year later (March 1998), OPP reported its progress to the SAP.

With respect to the comments that EPA has not considered common mechanism in these first nine assessments, the Agency acknowledges that it has not yet performed a cumulative risk assessment, because the methodology for conducting such assessments is still being developed. Since there are currently no standard methods for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop approaches to cumulative risk assessment. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, the International Life Sciences Institute (ILSI) is independently exploring appropriate methods and developing a framework for performing a cumulative risk assessment. ILSI held a workshop on this subject in September 1998, and will issue a report. The Agency will continue its ongoing efforts in this area along with examining the ILSI work and other sources of information in preparation for release of an Agency draft guidance document. This guidance document is currently scheduled for the late Summer or early Fall of 1999 with a 60-day comment period.

Until a method is available, EPA intends to complete risk assessments for individual OPs and proceed with the public process for development of risk mitigation strategies.

2. Comments Related to Additional Data, Data-Call-Ins, and Default

Assumptions

Comments: The Idaho Farm Bureau Federation, thirteen individual comments from PCO's, and the National Cotton Council encouraged EPA to use its data call-in (DCI) authority to obtain the data necessary to conduct realistic risk assessments. The Cotton Council noted that comments in the Public Docket from the registrants indicated that, in some cases, data had been submitted, but have not been reviewed or considered in the preliminary risk assessments. A common theme was that EPA should use actual data, particularly usage data, and avoid default assumptions in its assessments.

Response: In phase four of reregistration, EPA exercised its data call-in authority to require studies to upgrade chemical data bases to current scientific standards. Most of the OPs were subject to reregistration DCIs and registrants have been allowed ample time to submit those studies. EPA makes its reregistration and tolerance reassessment decisions on the best data that are available. Where data are incomplete EPA may compensate by using an additional uncertainty factor or making a reasonable health-protective assumption. This has long been EPA practice, and is reinforced by FQPA's emphasis on the importance of the use of uncertainty factors where data are incomplete.

It should be noted, however, that the OP risk assessments in the docket are "preliminary," and that many of these first nine assessments were completed prior to receipt of all required data. During the public comment and response period, EPA has continued its evaluations of available data, e.g., Monte Carlo analyses, for these first nine chemicals, and these evaluations have been incorporated into the revised risk assessments. In general, if additional, pertinent data are submitted prior to or during the comment periods, EPA will take these data into account in its final assessments and risk management options.

For a discussion of the sources of use and usage data and how EPA employs these data in its assessments, the reader is referred to a science policy paper entitled, "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management," which will be available shortly for public comment.

3. Comments Related to Inconsistencies in the Risk Assessments

Comments: NCAMP and others noted that the assessments for the nine OPs are inconsistent in format, level of refinement, assumptions used, and methods. For example, acute dietary risk is expressed in some assessments as a percentage of the reference dose (RfD), in others it is characterized by a margin of exposure. Drinking water risks are estimated in some assessments and not in others. It is not clear what risks are being aggregated and why.

Response: EPA acknowledges inconsistencies in the preliminary assessments for the first nine OPs. In many cases, the assessments were begun many months ago and have not been constantly updated to reflect new formats and methods. In the revised risk assessments we have made an

effort to ensure consistency in the assumptions and the levels of refinement that are applied, given the data available for each chemical. For example, for drinking water, we have calculated acute and chronic DWLOCs for all chemicals and compared them to the levels estimated to be found in water. In the revised assessments, all acute dietary risks are now expressed as a percentage of the acute population adjusted dose (aPAD). (The aPAD is the reference dose including the FQPA safety factor. If the FQPA safety factor has been removed, the aRfD and the aPAD are the same.) We have attempted to identify major risk contributors (i.e., commodities or use patterns that contribute most to the risk), and have refined the residue estimates to the extent possible with existing data, including use of USDA Pesticide Data Program (PDP) and FDA monitoring data in some cases. In an attempt to make the risk assessments easier to understand and compare, EPA has prepared risk summary and overview documents for each OP. These risk overview documents have been prepared in a standard, logical format and are intended to assist the reader by identifying key features and findings of the risk assessments, as well as highlighting any assumptions and refinements that have been used.

4. Comments Related to Application of the FQPA 10X Safety Factor

Comments: The Learning Disabilities Association and the NRDC commented that EPA failed to demonstrate the existence of reliable data for most OPs to justify departure from the use of the FQPA 10X safety factor.

Response: OPP has developed criteria for retaining, reducing, and removing the ten-fold safety factor provided for in the FQPA to account for special susceptibility of infants and children to the effects of pesticide exposures. These criteria involve a weight-of-evidence consideration of both the nature and severity of effects observed in young animals, as well as the adequacy of the data base for the chemical. OPP's rationale for these criteria has been reviewed at various stages of development by the SAP. OPP has completed a draft Standard Operating Procedure (SOP) that provides procedural guidance at the working level for making recommendations for retaining or modifying the 10-fold factor.

In addition, an Intra-Agency workgroup is looking at general considerations regarding the FQPA safety factor decisions such as: establishing procedures for consistency and documentation; ensuring the adequacy of the data set for decision-making; and establishing criteria for retaining or modifying the FQPA factor.

The Agency's policy for applying the FQPA 10-fold safety factor is currently one of the science policy issues being prepared for public comment. Both the SOP and the Intra-Agency workgroup draft guidance document were discussed at the May, 1999 SAP meeting and are available for viewing on the OPP SAP web page: http://www.epa.gov/pesticides/SAP/. An FR Notice announcing the availability of these documents for public comment is expected shortly, with revised documents anticipated in the Fall.

The question of what constitutes a reliable data base for making decisions related to the

FQPA safety factor is being thoroughly reviewed. Once that review process is completed, EPA may need to revisit its assessments and decide how best to incorporate the revised procedures into its ongoing decision making process.

5. Comments Related to Highly Exposed Populations

Comments: Both NCAMP and NRDC noted that EPA failed to consider the increased potential for pesticide exposure to "sentinel" populations, such as farm worker children.

Response: NRDC has petitioned the Agency to designate farm children as a major identifiable subgroup under the FQPA. The Agency is currently evaluating the scientific and legal issues raised in that petition. Specifically related to the preliminary risk assessments for the first nine OPs, EPA acknowledges that exposures to farm worker children were not evaluated separately, i.e., as a distinct population sub-group. However, based on the limited data currently available to characterize actual pesticide exposure to children of agricultural workers, such as a 1997 biomonitoring study by Loewenherz, Fenske and others (Environ. Health Perspect. 105:1344-1353), we believe that the exposure estimates developed by EPA using the Agency's Residential Exposure SOPs and other available information are reasonably inclusive of the exposures likely to be experienced by this sub-group.

EPA is concerned about the disproportionate exposure of farm children to pesticides and has several ongoing projects designed to both assess and reduce these exposures. Some of EPA's major efforts in this area are described below.

EPA's major external research program, Science to Achieve Results (STAR) program allocated funds in fiscal year 1996 for three years of research on the most urgent issues regarding exposure of children to pesticides. The studies are looking at major types of exposure (touching, eating, crawling, etc.) and at seasonal and locational differences, including agricultural settings. This research will support regulations and public education efforts that are more fully protective of children, for example through revised use restrictions and labeling requirements, and improved training and public information materials. Under the STAR program, the University of Arizona is assessing exposure of the children of seasonal and migrant laborers to agricultural pesticides. In addition, the University of Washington is assessing, on a comprehensive seasonal basis, children's exposures to organophosphate pesticides.

EPA's National Center for Environmental Research and Quality Assurance of the Office of Research and Development is funding a grant with the University of California at Berkeley for a five-year study, that began in August 1998, to quantify the exposure of children in agricultural areas of California to pesticides. The project will integrate biological research with community-based intervention efforts. The study will determine the impacts of pesticide exposure on children's growth and development. The University will also work with the farm worker community to investigate approaches for reducing these exposures.

Finally, based on recommendations from the Children's Health Protection Advisory Committee (CHPAC), EPA has committed to conduct a national assessment of implementation and enforcement of the Worker Protection Standard, including its effectiveness in addressing the safety needs of women and children as agricultural workers.

6. Comments Related to the Role of OPs in Integrated Pest Management (IPM)

Comments: The Michigan Agricultural Cooperative Marketing Association, the Grocery Manufacturers of America and the Southeastern Professional Fruit Workers Conference noted that the loss of OPs would reduce the effectiveness of entire IPM programs. The loss of any tool in the IPM arsenal can result in greater overall use of pesticides and the return to prophylactic use of pesticides. IPM should be explicitly addressed in the risk assessment process.

Response: EPA recognizes the importance of some OPs in IPM and resistance management programs. We intend to consider these factors, as appropriate, in our risk management decisions. Specifically, under FQPA, EPA cannot use the biological or economic importance of a chemical as a factor in determining allowable dietary risk. However, if risk management is necessary, these factors would be considered in determining which chemical uses are most critical and should be retained.

7. Testimonial Comments

Comments: Two individuals provided comments that were testimonial in nature, that is, they expressed opinions but provided little or no specific information for the Agency to respond to. One person offered the view that OP's are "nerve gas" and all use should be banned. Another offered his support for the continued availability and use of phorate, terbufos, chlorpyrifos, methyl parathion, fonofos, carbaryl, carbofuran, and bromacil (only first 5 are OPs; only terbufos and phorate were among the first nine OPs.) The commentor noted that yields on his farm would be reduced without these products, but provided no documentation to quantify the yield loss.

Response: EPA recognizes the diversity of views exhibited by these comments.

B. EPA's Response to Submitter - Specific Comments

1. Comments from Private Citizens

Comment: One commentor urged EPA to account for "enantiomer" toxicity in reassessing tolerances for the OPs. Enantiomers are mirror image molecules produced in the manufacture of organophosphate active ingredients. Specifically, the commentor raises concern over the possibility that specific enantiomers of these substances could be produced during manufacture, and that these enantiomers may be more toxic than other enantiomers that may be present. Hence, the risks posed by these substances could be greater than the risks anticipated by EPA.

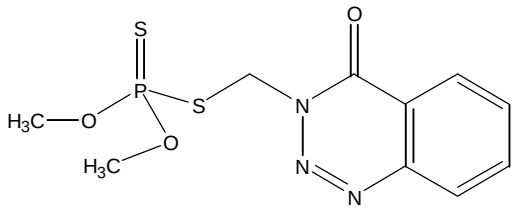
The commentor would like to know specifically how EPA took into account the possibility of specific enantiomers and their toxicity during its risk assessment of the nine organophosphorus compounds and what procedures ensure that the current toxicity testing of active ingredients will reveal any potential problem with enantiomer contamination.

The commentor also referred to incidents "in Pakistan or Afghanistan and in the SW United States" related to the toxic effects of enantiomers of organophosphorus compounds in which “hundreds of people were killed.”

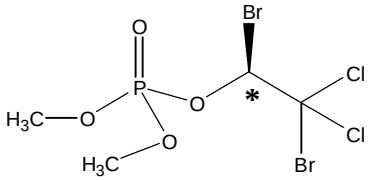
The American Crop Protection Association (ACPA) submitted a comment to the docket which responded that normal toxicity testing for registration will test all of the enantiomers together. They also said that of the nine OPs only naled has a chiral center (a carbon atom bonded to four different groups), none of the others can possibly have enantiomers.

Response: Enantiomers of a given substance are isomers whose mirror images are not superimposable. While enantiomers of a given substance have identical physicochemical properties (except in the direction in which they rotate a plane of polarized light), they may vary in toxicity and, therefore, pose different risks to human health or the environment. In a given manufacturing process it is possible for more than one specific enantiomer of the product substance to form. It is also possible that one enantiomer may be produced more readily than another enantiomer, and may predominate in the commercial product. Even if an enantiomer is formed in low concentration relative to another enantiomer during synthesis of a commercial product, it may still contribute significantly to the overall risk of the product if its toxicity is greater than the toxicity of the other enantiomer. EPA's Office of Pesticide Programs (OPP) routinely evaluates the manufacturing processes used to synthesize pesticides as part of its process to evaluate the risks posed by pesticides. The primary purpose of evaluating a manufacturing process of a given pesticide is to ascertain the composition of the technical product with regard to overall risk to human health and the environment. The evaluation includes an analysis and consideration of the feedstocks, reagents, catalysts, solvents and any other substances used in the process; reaction conditions; pesticide yield; byproducts, and any other substances that are known, or could reasonably be anticipated to form under the reaction conditions of the process. OPP also considers any impurities in the reactants or other substances used in the synthesis that may contaminate the technical product and contribute to overall risk.

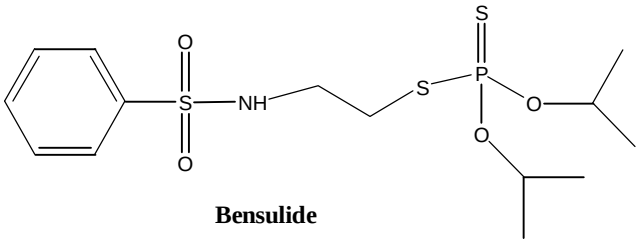
The structures of the nine organophosphorous substances are shown below. Naled has a chiral carbon atom (indicated with an asterisk), and fenamiphos, isofenphos and profenofos have chiral phosphorus atoms. Hence, two enantiomers are possible for naled, fenamiphos, isofenphos and profenofos. The other substances shown do not have chiral atoms and, therefore, it is not possible for them to exist as enantiomers. The Agency does not know the relative ratios of the specific enantiomers in the technical products of naled, fenamiphos, isofenphos and profenofos. However, the mammalian toxicity studies submitted by the registrants correspond to the technical products as manufactured, and reflect the actual toxicity of the technical products. The same is also true for the ecotoxicity studies submitted to the



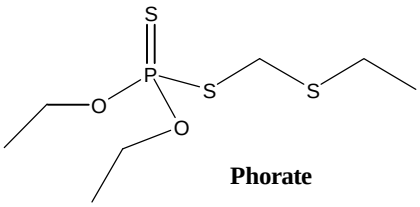
Azinphos-methyl



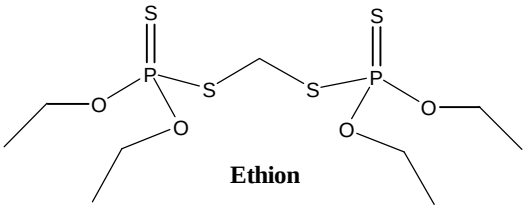
Naled



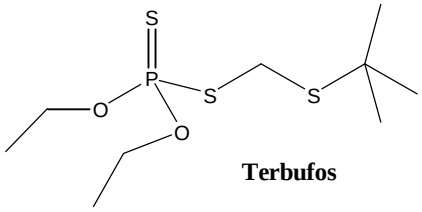
Bensulide



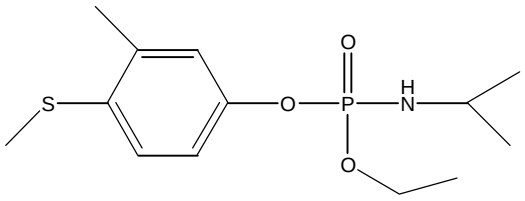
Phorate



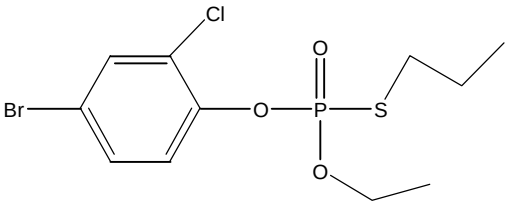
Ethion



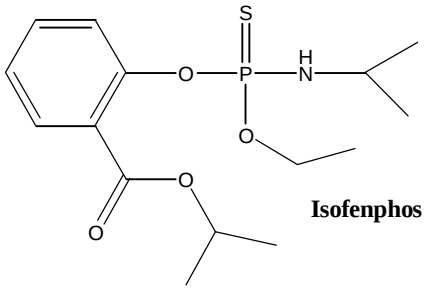
Terbufos



Fenamiphos



Profenophos



Isofenphos

Agency. Therefore, even if one of the two enantiomers of any of the substances is substantially more toxic than the other enantiomer, and is present in the technical product, its toxicity would be expressed in the mammalian and ecotoxicity data submitted to the Agency and used in OPP's risk assessment of the technical product.

OPP also considers environmental fate during its risk assessment of a given pesticide. Environmental fate laboratory studies are typically conducted with a pure sample of the pesticide, radiolabelled at least at one site of the molecule. Separation of specific enantiomers of a pure sample prior to the environmental testing is not required, and usually not performed. The Agency recognizes, however, that a specific enantiomer of a substance could convert to another enantiomer under actual environmental conditions. Environmental photolysis, for example, may lead to interconversion of one enantiomer to another. OPP evaluates geometrical, configurational and/or conformational isomer interconversions, but only for those chemicals known to show specific isomer bioactivity. That is, one or more of the isomers are the only ones associated with pesticidal activity over the other isomers.

For naled, fenamiphos, isofenphos or profenofos, OPP does not have optical rotation data on any of the pure active ingredients to rule out or confirm the prevalence of one enantiomer over the other, or to conclude that the active ingredient exists as an equimolar (racemic) mixture. The environmental fate studies submitted for these substances were not intended to follow the fate of individual enantiomers in regard to enantiomeric interconversions. Hence, OPP does not know to what extent, if at all, the individual enantiomers of naled, fenamiphos, isofenphos or profenofos interconvert in the environment. In addition, data are lacking regarding the mammalian toxicity and ecotoxicity of the individual enantiomers of these substances. Because of these data gaps, there is no basis from which OPP can consider in its risk assessments of these substances the possibility of, and extent to which the specific enantiomers of these substances may interconvert in the environment and the impact that such interconversions may have on human health and the environment.

It should be noted that EPA has recently published a Federal Register notice requesting public comment on how the Agency should handle registration of pesticide active ingredients (AIs) that are composed of chemical isomers. Among other issues, the notice solicits comment on whether or not an AI originally registered at a particular proportion of isomers should be subsequently registered as a new AI when purified for one or more chemically active isomers. The notice was published in the Federal Register on April 28, 1999, Volume 64, Number 81, Pages 22863-22865. Comments, identified by the docket control number "OPP-00580", must be received by June 28, 1999. EPA will consider comments received in developing a policy on registration of isomeric active ingredients.

As to the commentor's reference to large numbers of deaths resulting from OPs, EPA has no record of pesticide poisoning incidents of the magnitude described. One incident was reported in Pakistan among malaria workers. In this instance there was an abrupt shift from DDT to malathion use for mosquito control. One of the malathion batches was contaminated with the

more toxic isomalathion, resulting in numerous exposures and possibly five deaths.

Anyone with specific knowledge of harmful incidents related to OP use or OP contamination with enantiomers is encouraged to submit them to EPA, so they can be considered in our risk assessments. Incident information is most useful if it contains sufficient detail to determine the circumstances of exposures, e.g., was it an accident or misuse, what symptoms were observed, how severe and long lasting were the symptoms, etc.

2. Comments from Growers, Commodity and Marketing Groups

Comment: The Idaho Farm Bureau Federation felt that the criteria defining all OPs as having a common mechanism of toxicity are too broad. EPA should take time to develop appropriate criteria for common mechanism, gather actual data rather than rely on conservative default assumptions, and communicate decisions to all stakeholders. The Federation supports Vice President Gore's directive to have an open and transparent process, a reasonable transition to alternative products, and the use of sound science. They believe that sound science dictates not allowing decisions to be driven by a statutory time frame. The Federation offers assistance with usage questions.

Response: EPA is committed to the principles outlined by Vice President Gore. It is primarily for that reason that the Tolerance Reassessment Advisory Committee (TRAC) was formed and the pilot process for increased public participation in pesticide decisions was developed. However, EPA must balance the goal of providing for greater transparency and participation in development of science policy with its mission to ensure the safety of the food supply and the health of consumers--especially children, workers, and the environment. In order to accomplish our mission through timely decision making, EPA has established an ambitious schedule for completion of individual OP risk assessments and development of risk management options. It should also be noted that FQPA does establish a statutory deadline to complete the reassessment of existing tolerances by 2006, and the Agency is making every effort to comply with that deadline.

See also responses to II.A.1 and II.A.2 above.

Comment: The National Cotton Council notes that registrant comments in the dockets indicate relevant data were not considered in the assessments. Publishing risk assessments that are incomplete and thus inaccurate does not enhance the process, exemplify sound science, or inspire confidence in the growers that EPA will make good decisions. The Council is concerned that exposures from gin trash as a feed additive are grossly overestimated. No cotton uses should be canceled based solely on unacceptable risk resulting from gin byproducts using current EPA assumptions. (Note: OPs with cotton uses include azinphos-methyl, phorate, profenofos, naled, dicrotophos, and DEF (tribufos). The Council is working with the Agency to “adjust” these assumptions.

Response: EPA representatives recently (10/13/98) met with a delegation from National Cotton

Council (NCC) in response to their request to discuss cotton gin byproducts (CGB) and its proportion in livestock feeds. In addition to members of the NCC, representatives of cotton ginners associations (Texas Cotton Ginners Association, Southeastern Cotton Ginners Association, and the California Cotton Ginners Association) were present. These experts are familiar with CGB, its volume of production in the USA, and its use as animal feed.

EPA discussed how a risk assessment is performed, i.e., how CGB are factored into the beef and dairy cattle diets and how potential transfer of residues to meat and milk could therefore affect a person's daily dietary intake of pesticide residues. Table 1 of OPPTS Test Guidelines Series 860 currently lists CGB as a raw agricultural commodity as comprising up to 20% of the diet of beef and dairy cattle.

Representatives of the ginners associations agreed that in some parts of the country CGB are fed at up to 10% of the diet to beef cattle when the cattle first enter the feed lot. CGB are then reduced to approximately 3% in the finishing rations. Based on this information, the NCC has asked EPA to reconsider how CGB are currently listed in Table 1.

EPA asked the NCC to provide detailed information concerning the disposition and use of CGB. Information submitted should be able to be independently verified by OPP. The NCC agreed to submit a protocol for obtaining such information.

See also response to II.A.2 above.

Comment: The Michigan Agricultural Cooperative Marketing Association notes that phorate fits well into growers established IPM plans to minimize pest resistance. Its loss would reduce effectiveness of the entire IPM program. Azinphos-methyl is essential to blueberries and tart cherries-- Michigan is a leading producer of these commodities in the US. No quantitative loss estimates were are given. The Association encourages EPA or USDA to obtain from growers on a national level the necessary use data which will satisfy the crop-pest-pesticide requirements so that proper FQPA decisions can be made.

The Association notes that the Michigan Department of Agriculture is completing a research project designed to evaluate the impacts of various production and handling practices on pesticide residues on food. The project was funded by EPA Region 5 and will test samples at the farm gate and at various stages during processing to quantify residue reductions. The Association urges EPA not to make any determinations--interim or final--until science policy issues are resolved; they acknowledge the magnitude of the task facing EPA in implementing FQPA and offer assistance.

Response: EPA has contacted Michigan State University to determine the scope and timing of the research that was described in this comment. The project is currently focusing on apples, peaches, blueberries, cucumbers, squash and potatoes, but other commodities are planned. The analysis of field data is scheduled for completion in 1999. Until these data are submitted and reviewed, we

cannot comment on how they will impact current assessments. However, EPA notes that this type of data, i.e., linking actual application rates and practices with residue reduction from various processing techniques, could be very useful in determining pesticide-crop specific processing factors for refining residue estimates. If these data are received in a timely manner, they can be considered in EPA's ongoing assessments.

See also response II.A.6 above.

Comment: US Apple Association has worked with the Agency to develop data that could refine residue estimates and has submitted such data to the Agency. However, it is impossible to ascertain from the preliminary risk assessment in the docket, what data were used in the azinphos-methyl apple assessment.

Response: This comment primarily relates to azinphos-methyl; however, a general discussion of how EPA employs use and usage data may be helpful. EPA has various sources for these data including USDA, California EPA, National Center for Food and Agriculture Policy, grower groups, as well as proprietary sources. These data tend to be more robust for major crops such as corn and cotton, and less so for minor crops. It is for these minor crops that usage data from growers can be most useful. In general, EPA incorporates use and usage data in a number of ways to assess dietary risk. Initial refinement involves incorporating the percentage of the crop that is actually treated (%CT). Further refinements involve applying processing factors, and calculating residue decline and residue degradation where data are available to quantify these residue reductions. Additionally, an apple cooking study on baby food could reduce the estimated dietary risk. Also, single serving data on apples could reduce or increase the estimated dietary risk.

Growers and others frequently point out that the actual or typical application rates and frequencies are lower than labeled rates and that actual PHIs are longer than those specified on the product labels, and that these typical values should be used in EPA's risk assessments. This information is useful to the Agency only if it is accompanied by data to quantify residue reductions from longer PHIs, lower application rates, etc. Further, in order for the Agency to be able to rely on lower application rates and longer PHIs in its risk management decisions, product labels may need to be revised to reflect these refinements.

In its refined risk assessments, EPA has tried to show clearly which refinements have been applied to each crop. For example, for azinphos-methyl the revised risk assessment has an appendix table of crop by crop descriptions of specific data used in the revised analysis. This table clearly indicates that the Agency used USDA Pesticide Data Program (PDP) and FDA monitoring data for 80% of foods treated.

Comment: The Grocery Manufacturers of America emphasized four general points: 1) the importance of sound scientific principles; 2) the importance of using all available data to the maximum extent feasible; 3) ensuring the availability of chemicals required for IPM programs; and 4) validate all models and methods before use for regulatory purposes.

EPA should use both monitoring data and processing studies wherever possible, including PDP, and FDA data and actual use practices rather than theoretical maximums and assumptions.

Response: Until now, EPA has used PDP monitoring data in acute dietary assessments only for blended commodities, such as apple sauce and tomato paste. EPA has not used PDP data for single serving commodities, such a single fresh apple or a baked potato, because PDP data are derived from composite samples, and do not represent the highest concentrations that could be found in individual single servings. It is these potentially high residues that are of concern for acute dietary risk assessments. However, recently EPA has developed a statistical method to determine the range of residue values comprising composited samples for certain commodities. This method has been applied to several of the acute dietary assessments for the first 9 OPs, including azinphos-methyl. It is currently undergoing additional peer review.

See also responses to II.A.2, II.A.3, and II.A.6 above.

3. Comments from Environmental and Consumer Groups

Comment: The National Coalition Against the Misuse of Pesticides (NCAMP) questions why EPA has made only nine assessments available to the public and why the Agency has ignored common mechanism. NCAMP compared methodology across all nine assessments and found inconsistencies in methods, different ways of combining risks, different assumptions, data sources used, and formats.

For example, in the Human Health Assessments NCAMP feels that real world exposures such as drift, routine misuse, exposure to multiple chemicals, and exposures to children of farm workers were ignored. Similarly, for Ecological Risk Assessments, multiple routes of exposure should be considered, e.g. direct application, runoff, drift, bioaccumulation, etc. Direct and indirect (food chain) effects should also be considered.

For all assessments, not all inerts, contaminants, metabolites and degradation products were considered. EPA ignored sources such as NCAMP, other non-profits and Agencies, and open literature for incident and other information. EPA's assessments fail the criteria of transparency; EPA should produce a guide to all OP risk assessments summarizing hazard, exposures and why risks have not been combined.

Response: EPA considers, on a routine basis, a number of the factors that NCAMP lists as omissions in our risk assessments. Some of these considerations are standard procedures and as such, are not mentioned in every risk assessment. For example, both technical active ingredients and end-use products are tested for comparative toxicity and composition. If inerts, contaminants, degradates or metabolites of toxicological concern are identified, we can require additional data, both toxicity and environmental fate data, if necessary, on those substances. EPA's Inert Ingredients Policy identified inerts of most concern, required testing and labeling for certain classes of inerts, and has resulted in a shift from more to less toxic inerts in pesticide products.

When studies are brought to the Agency's attention, EPA can and has used information from the open literature for its risk assessments. For example, EPA's "Hazard Assessment of the Organophosphates" (July 1998) mentions literature studies as part of the weight-of-evidence considerations for acephate, chlorpyrifos, malathion, and methamidophos.

EPA routinely considers incident information in its risk assessments. The Agency maintains data bases of incidents related to human poisoning from pesticides, contamination of water resources, and wildlife exposures and die-offs due to pesticide exposure. We work with states, particularly California, other government agencies, and private organizations, such as Poison Control Centers to obtain accurate and up-to-date information related to pesticide exposure incidents of all kinds. We encourage NCAMP, through this public comment process, to actually provide EPA with any information that they may have relevant to the risk assessment of the OPs, rather than simply noting the existence of such information.

See also responses to II.A.3. and II.A.5 above.

Comment: The Learning Disabilities Association (LDA) notes that none of the first nine organophosphate chemical risk assessments retained the FQPA 10X factor. In the Report of the FQPA Safety Factor Committee, EPA found no evidence of enhanced susceptibility for 33 of 40 OPs. LDA seriously questions this conclusion based on two factors. First, is the inadequacy of the developmental neurotoxicity database. This is the only study that looks at functional effects like learning and memory. If EPA does not have developmental neurotoxicity data, how can we be sure there are no functional effects. Second is EPA's tendency to disregard offspring toxicity as "secondary" to maternal toxicity. LDA believes that even if developmental effects occur at higher doses than maternal, the maternal effects could be transient, and the effects in offspring might be permanent.

LDA requests EPA to defer final decisions on the FQPA 10X safety factor for all OPs until the expert panel recommendations for what constitutes an appropriate toxicity and exposure data base for making 10X determinations are available in late December.

Response: EPA's process for reviewing current procedures related to the 10-fold FQPA safety factor are described in detail above in section II.A.4. The Agency is currently beginning the public participation process to develop risk mitigation for the first nine OPs. Developing and implementing interim mitigation for these chemicals now does not preclude additional mitigation and/or data requirements in the future in response to new or revised policies and guidance. With few exceptions, the Agency's decisions related to the OPs cannot be considered final until a cumulative assessment has been conducted.
See also response to II.A.4 above.

Comment: The Natural Resources Defense Council (NRDC) submitted a copy of their report, "Putting Children First," and provided comments on four broad issues: 1) EPA fails to demonstrate the existence of reliable data for most OPs to justify departure from the use of FQPA

10X safety factor; 2) preliminary assessments do not provide reasonable certainty of no harm, e.g. EPA did not consider "sentinel" population of farmworker children; 3) EPA must conduct a cumulative assessment; and 4) often, e.g., for azinphos-methyl, occupational risks are unacceptable even with maximum mitigation. These should be eliminated expeditiously.

Response: EPA intends to complete risk assessments for individual OPs, taking into account any comments received during the public comment period. For the first nine OPs, the public comment period closed on the preliminary risk assessments in October, 1998. According to the plan developed by the TRAC, EPA will revise the risk assessments, respond to comments on the preliminary risk assessments, hold a Technical Briefing, and work with USDA and stakeholders to solicit risk management ideas.

See also responses to II.A.1, II.A.4, and II.A.5 above.

4. Comments from Other Federal Agencies

Comment: The Fish and Wildlife Service, Division of Environmental Contaminants, pointed out that all nine of the OPs have Final Biological Opinions (1989) for Endangered Species. FWS recommends that EPA implement, at a minimum, via label modifications and county bulletins, the applicable Reasonable and Prudent Alternative measures identified in 1989 Biological Opinions. EPA should also implement the risk reduction and mitigative measures identified in the OP ecological risk assessment documents to reduce hazards to non-target organisms.

Response: EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has included the pesticide use provisions from the 1989 Biological Opinion (as well as other opinions) or equivalent protective measures in the over 300 bulletins that have been completed and distributed.

The mitigation measures suggested in the preliminary ecological risk assessments, along with other measures that may be put forward during the comment period, will be considered in developing risk management strategies for these nine OPs.

5. Comments from Universities and Extension Services

Comment: The Texas Agricultural Extension Service provided a preliminary economic assessment of the withdrawal of certain FQPA target pesticides on prominent vegetable crops (onions, melons, carrots, crucifers and peppers) in the Rio Grande Valley of Texas. The report examines changes in yield and estimated economic losses in farm revenue, from the loss of various chemicals and combinations of chemicals including the OPs, bensulide, diazinon, dimethoate, disulfoton, chlorpyrifos. The assessment includes several other non-OP pesticides.

Response: This information has been provided to our Biological and Economic Analysis Division

and to the Chemical Review Managers for the listed chemicals for use in developing risk mitigation options. Under the provisions of FQPA, EPA can not use benefits information as a rationale for exceeding acceptable dietary risk levels. However, such information could be useful in considering risks and developing transition strategies, if such strategies become necessary.

Comment: The Southeastern Professional Fruit Workers Conference, the annual meeting of applied fruit scientists (held at Clemson University in October, 1998) provided their evaluation of the OPs (and other pesticides) that are crucial in resistance management and IPM programs for crops in their area.. The group identifies opportunities for mitigation (primarily reductions in numbers of applications and increased PHIs). *(Note: This comment was submitted after the dockets for the first nine OPs closed. However, because it pertains to some of the first nine, we have chosen to address it in the first response document.)*

Response: This information has been provided to our Biological and Economic Analysis Division and to each of the Chemical Review Managers for the chemicals named in the analysis. This type of information is useful to the Agency in determining the feasibility of mitigation such as reduced frequency and timing of pesticide applications, and in considering risk trade-offs, where appropriate.